

## **REMARKS**

### **I. Amendments**

By this amendment, claims 1 and 5 have been amended and claims 4 and 7-10 have been cancelled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

### **II. Acceptability of the Drawings**

Applicants note that seven pages of drawings (Figures 1-7) accompanied the specification as originally filed. Applicants respectfully request that the Examiner indicate whether or not the drawings are acceptable. If the drawings are unacceptable, Applicants respectfully request that they be provided a Notice of Draftsperson's Patent Drawing Review.

### **III. Discussion of the Election**

Claims 1-3, 5 and 6 are pending, having been elected previously. The remaining claims were withdrawn by the Examiner. By this amendment the withdrawn claims have been cancelled without prejudice to the filing of future continuing applications.

The pending claims have also been limited to SEQ ID NO:1, in accordance with the restriction requirement.

Therefore Applicants assert that the present claims as amended are in conformance with the restriction requirement.

#### **IV. Discussion of the Rejection of Claims 1 and 2 under 35 U.S.C. Sec. 101**

Claims 1 and 2 have been rejected under 35 U.S.C. 101 as allegedly directed to non-statutory subject matter. Applicants respectfully traverse the rejection.

By this amendment, claim 1 has been amended to recite an isolated protein. Applicants assert that claim 1 as amended recites statutory subject matter.

Claim 2 depends upon claim 1. Applicants assert that the more specific dependent claim also recites statutory subject matter.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 101 rejection of claims 1 and 2.

#### **V. Discussion of the Rejection of Claims 1-3, 5 and 6 under 35 U.S.C. Sec. 101**

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. 101 as allegedly lacking utility. Applicants respectfully traverse the rejection.

The Examiner has stated on page 4 of the Office Action that “[n]o evidence has been provided to support this assertion that the protein is specifically expressed in these tissue systems (trachea, bronchus, lung related tissue), and not in other systems.” Applicants disagree, and wish to draw the Examiner’s attention to Example 2 on page 68 of the specification, wherein an analysis of expression sites was performed, and confirmation of expression in limited tissues was indicated.

If the Examiner has no additional documentation to support the argument that the protein is expressed in other systems, Applicants respectfully submit that their assertion is correct.

One skilled in the art can recognize therapeutic indications for a protein so expressed. Examples of diseases which the isolated protein as set forth in claim 1 as amended may affect are described in the specification on page 4, in paragraph 24.

According to MPEP Sec. 2107, if the Applicant has asserted that the claimed invention is useful for any particular practical purpose, and the assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility should not be imposed.

Applicants believe that they have met the threshold requirements for utility, and thus Applicants believe that the aspect of their invention set forth in independent claim 1 meets the utility requirements. As pending claims 2, 3, 5 and 6 depend upon claim 1, Applicants assert that the utility requirement has also been met with respect to the dependent claims.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 101 rejection of claims 1-3, 5 and 6.

## **VI. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph**

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. Sec. 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse the rejection.

Applicants hereby incorporate their arguments found in Sec. V above, which are also applicable to this rejection.

In addition, Applicants also provide the following comments, should any other aspect of enablement be questioned by the Examiner.

On page 66, information regarding deposits of relevant materials are described. Applicants assert that the deposits prove enablement of claims 1-3 and 6.

As to claim 5, Applicants assert that this claim as amended is also sufficiently enabled by the descriptions in the specification such as page 57, paragraph 304 – page 58, paragraph 312 *inter alia*.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

## **VII. Discussion of the Rejection under 35 U.S.C. Sec. 112, Second Paragraph**

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. Sec. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection. Each aspect of the rejection will be discussed in the following paragraphs.

In the first aspect of the rejection, the phrase “substantially identical” in claim 1 has been objected to as allegedly vague. By this amendment, that phrase has been deleted, thereby rendering this aspect of the rejection moot.

In the second aspect of the rejection, the phrase “partial peptide” in claim 2 has been objected to as allegedly vague. As this phrase is described in the specification on page 10, paragraph 68 – page 11, paragraph 75, Applicants disagree that the phrase is unclear.

In the third aspect of the rejection, the phrase “salt thereof” has been objected to. As salts are described in the specification on page 11, paragraph 75, Applicants disagree that the phrase is unclear.

In the fourth aspect of the rejection, claim 5 has been objected to as allegedly lacking essential steps. By this amendment, claim 5 has been re-written in accordance with the

teachings of the specification at page 57, paragraph 304 – page 58, paragraph 312. Therefore the amendment of claim 5 introduces no new matter into the specification.

In the fifth aspect of the rejection, claims 5 and 6 have been objected to as allegedly indefinite in the recitation of the phrase “promoting or inhibiting”. The phrase has been deleted from claim 5 by this amendment. Yet the Applicants believe that this phrase in claim 6 is sufficiently clear, and respectfully request that the Examiner consider the teachings of the specification at page 34, paragraph 187. Promoters and inhibitors are discussed therein. Compounds could potentially promote or inhibit activity; it would not be clear which activity the compounds would have until they were tested. The uncertainty is the reason for the screening, but it does not make the phrase “promoting or inhibiting” indefinite. By contrast, Applicants assert that those skilled in the art would comprehend the meaning of the phrase. Moreover, such language is found in issued U.S. patents such as in claim 3 of U.S. Patent No. 6,682,917 and claims 9 and 10 of U.S. Patent No. 6,498,019.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

#### **VIII. Discussion of the Rejection under 35 U.S.C. Sec. 102(a) over Rosen *et al.***

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. Sec. 102(a) as allegedly being anticipated by Rosen *et al.* (WO 98/45712). Applicants respectfully traverse the rejection.

By this amendment, Applicants have amended claim 1 to delete the phrase “substantially identical”. As the Examiner has indicated that the art protein has 81.8% sequence identity to the amino acid sequence of SEQ ID NO: 1, Applicants respectfully assert that the cited reference does not anticipate claim 1 as amended.

Claims 2, 3, 5 and 6 depend upon claim 1. Applicants assert that the more specific dependent claims are also not anticipated by the cited reference.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(a) rejection.

## IX. Conclusion

Reconsideration of the claims and allowance is requested.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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